

CLAIMS:

1. A composition having a viscosity of 150cp or less at 25°C and comprising (i) chitosan, a salt or derivative thereof or a salt of a derivative thereof, (ii) a polyol-phosphate or sugar-phosphate salt, (iii) a plasticizer, and (iv) a therapeutic agent.
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2. The composition according to claim 1 in the form of an aqueous solution or suspension.
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3. The composition according to claim 1, which forms a gel at a temperature 30 °C or greater.
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4. The composition according to claim 3, which forms a gel in 15 minutes or less at a temperature of from 30 to 40 °C.
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5. The composition according to claim 4, which forms a gel in 15 minutes or less at a temperature of from 35 to 37 °C.
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6. The composition according to claim 1, wherein the plasticizer is triethyl citrate.
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7. The composition as claimed in claim 1, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof has a molecular weight of 4000 Dalton or greater.
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8. The composition according to claim 7, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof, has a molecular weight of from 50,000 to 300,000 Dalton.
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9. The composition according to claim 1, comprising chitosan base or a chitosan derivative that has been formed by bonding of acyl or alkyl groups with the hydroxyl groups of the chitosan or a nitrate, phosphate, sulphate, citrate, hydrochloride, glutamate, lactate or acetate salt of chitosan.

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10. The composition according to claim 1, wherein the chitosan has a degree of deacetylation of 40 % or greater.

10 11. The composition according to claim 12, wherein the degree of deacetylation is from 70 to 90 %.

15 12. The composition according to claim 1, comprising from 0.25 to 3.0 % w/v of chitosan, a salt or a derivative thereof or a salt of a derivative thereof expressed as chitosan base.

13. The composition according to claim 12 comprising from 0.45 to 1.5 %w/v of chitosan, a salt or a derivative thereof or a salt of a derivative thereof expressed as chitosan base.

20 14. The composition according to claim 1, wherein the therapeutic agent is present in solution or as a suspension.

15. The composition according to claim 1, wherein the polyol-phosphate salt is β -glycerophosphate disodium.

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16. The composition according to claim 1, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.25 to 3.0 % w/v.

5 17. The composition according to claim 16, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.75 to 2.0 % w/v.

18. The composition according to claim 1, comprising from 0.05 to 5.0 % w/v of the plasticizer.

10 19. The composition as claimed in Claim 18 comprising from 0.2 to 1.0 % w/v of the plasticizer.

15 20. The composition according claim 1, additionally comprising ascorbic acid.

21. The composition according to claim 20 comprising from 0.01 to 0.2 % w/v ascorbic acid.

20 22. The composition according to claim 1, wherein the therapeutic agent is a polar drug, a polypeptide, a gene or a gene construct.

23. The composition according to claim 22, wherein the therapeutic agent is insulin, calcitonin, leuprolide, luteinising hormone releasing hormone, growth hormone or a growth hormone releasing factor, naratriptan, sumatriptan, zolmitriptan, rizatriptan, eletriptan, frovatriptan, alnitiidan, avitriptan, almotriptan, apomorphine, sildenafil,

alprostadil, diamorphine, hydromorphone, buprenorphine, fentanyl, oxycodone, codeine, morphine or morphine-6-glucuronide.

24. A drug delivery device suitable for delivery of a composition via one or more of the nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular routes or a dose cartridge for use with such a device loaded with a composition as defined in claim 1.

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25. A process for the preparation of the composition as defined in claim 1, which process comprises mixing a solution comprising chitosan or a salt or derivative thereof or a salt of a derivative thereof with a solution comprising a polyol-phosphate or sugar-phosphate salt.

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26. The use of the combination of chitosan or a salt or derivative thereof or the salt of a derivative thereof, a polyol-phosphate or sugar-phosphate salt and a plasticizer in the manufacture of a medicament for use in the transport of a therapeutic agent across a mucosal surface in an animal.

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20 27. The use of the combination of chitosan or a salt or derivative thereof or the salt of a derivative thereof, a polyol-phosphate or sugar-phosphate salt and a plasticizer in the manufacture of a medicament for nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery.

25 28. The use of a composition as defined in claim 1, in the manufacture of a medicament for use in the transport of a therapeutic agent across a mucosal surface in an animal.

29. The use of a composition as defined in claim 1, in the manufacture of a medicament for nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery.

5 30. The use according to claim 26, wherein the medicament is intended for local action.

31. The use according to claim 26, wherein the medicament is intended for systemic action.

10 32. The use of a composition as defined in claim 1, in the administration of a therapeutic agent for transport thereof across a mucosal surface in an animal.

15 33. The use of a composition as defined in claim 1, in nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery of a therapeutic agent to an animal.

20 34. The use according to claim 32, wherein the therapeutic agent is intended for local action.

35. The use according to claim 32, wherein the therapeutic agent is intended for systemic action.